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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,954	07/22/2002	Stephen Arkinstall	ARKINSTALL=1	4903
1444 7590 11/03/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER COLEMAN, BRENDA LIBBY	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 11/03/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/070,954	Applicant(s) ARKINSTALL ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-12,20-22,27-31 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-12,20-22,27-31 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 2, 5-12, 20-22, 27-31 and 35 are pending in the application.

This action is in response to applicants' amendment dated July 22, 2009. Claims 1, 2, 5, 7, 8, 21 and 22 have been amended and claims 3 and 36 have been canceled.

Note: The applicants' are reminded of the manner of making amendments.

37 CFR § 1.121 Manner of making amendments in application.

(c) Claims. Amendment to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an exiting claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims in the amendment document will serve to replace all prior versions of the claims in the application. In the claim listing, the **status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).**

The following claim(s) fail to properly identify the status of the claims:

a) **Claims 11 and 12 indicate (previously presented) after the claim number. Claims will not print properly if the status identifier is not properly stated, i.e. (Currently amended).**

Response to Amendment

Applicant's arguments filed July 22, 2009 have been fully considered with the following effect:

1. With regards to the provisional obviousness-type double patenting rejection of claims 1-3 and 5-41 labeled paragraph 1) over copending Application No. 10/381,200

maintained in the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 1, 2, 5-12, 20-22, 27-31 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No, 10/381,200, for reasons of record and stated above.

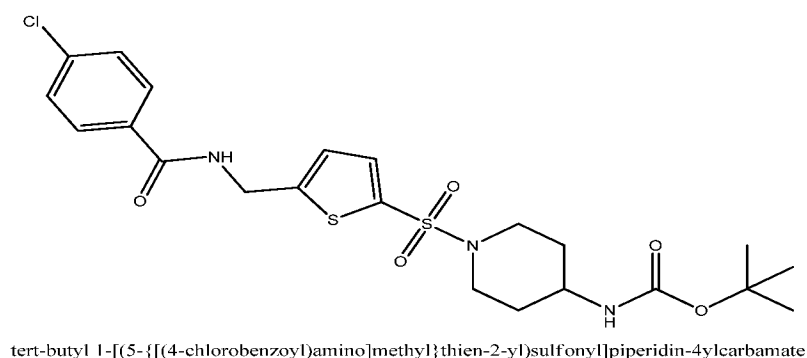
2. With regards to the provisional obviousness-type double patenting rejection of claims 1-3 and 5-41 labeled paragraph 2) over copending Application No. 10/381,665 maintained in the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 1, 2, 5-12, 20-22, 27-31 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No, 10/381,665, for reasons of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections, labeled paragraph 6c), d), e), f), i), j), k), m), n), q), r), s), w), z), aa), dd), ee), ff), jj), ll), mm), pp), qq), rr) and ss) maintained in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections, labeled paragraph 6b), g), h), l), o), p), t), u), v), x), y), bb), cc), gg), hh), ii), kk) and nn) maintained in the last office the applicant's amendments and arguments have been fully considered, however they were not found

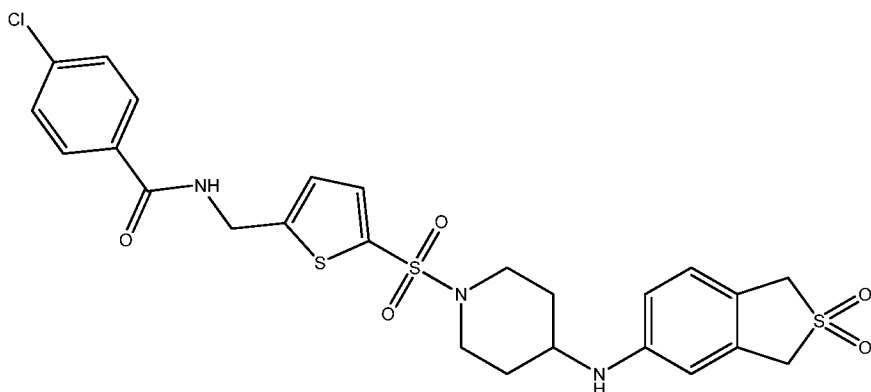
persuasive. The applicants' stated that Claim 1 has been amended to recite the specific groups that can be substituents. However, the definition of the substituents on the piperidiny moiety of Y does not include the substituents as claimed herein.

b) Claim 11 recites the limitation "tert-butylcarbamate" in the 8th species on page 12. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L² is COOR³ and R³ is tert-butyl however, the substituent for L² is actually -NHCOOtert-butyl as set forth in the species below:



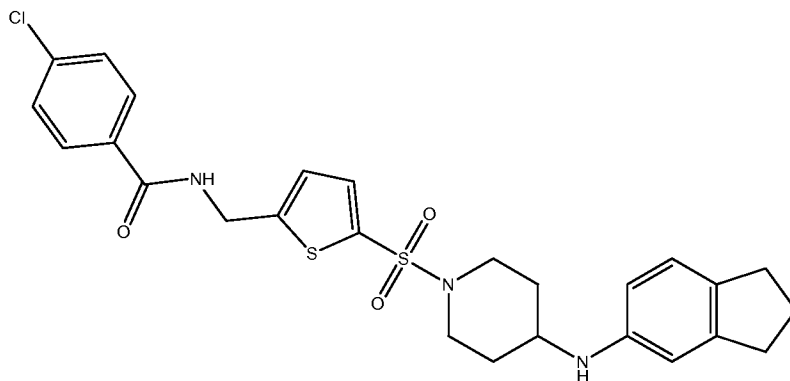
g) Claim 11 recites the limitation "2,2-dioxido-1,3-1,3-dihydro-2-benzothien-5-yl" in the 3rd species on page 19. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L² is NR³R³ and R³ is heteroaryl however, the substituent R³ is actually not heteroaryl but heterocyclic as set forth in the species below:

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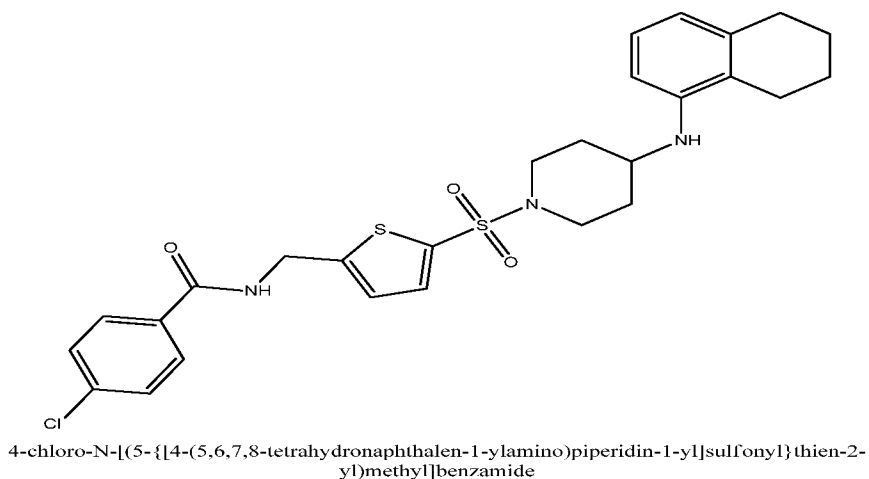
4-chloro-N-([5-([4-[(2,2-dioxido-1,3-dihydro-2-benzothien-5-yl)amino]piperidin-1-yl)sulfonyl]thien-2-yl)methyl]benzamide

h) Claim 11 recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 4th species on page 19. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is heteroaryl however, the substituent R^3 is actually not heteroaryl but carbocyclic as set forth in the species below:

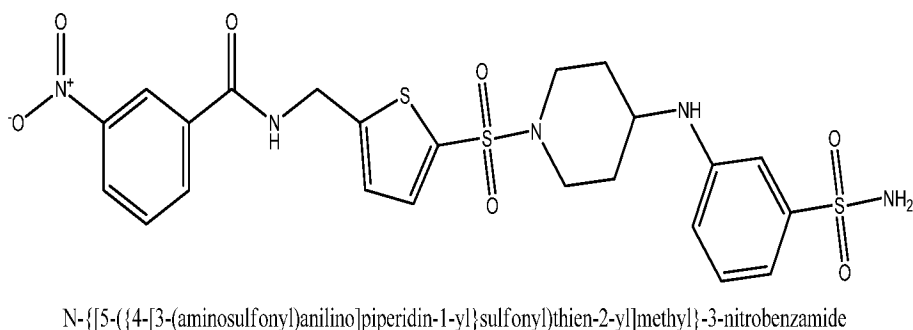


4-chloro-N-([5-([4-(2,3-dihydro-1H-inden-5-ylamino)piperidin-1-yl)sulfonyl]thien-2-yl)methyl]benzamide

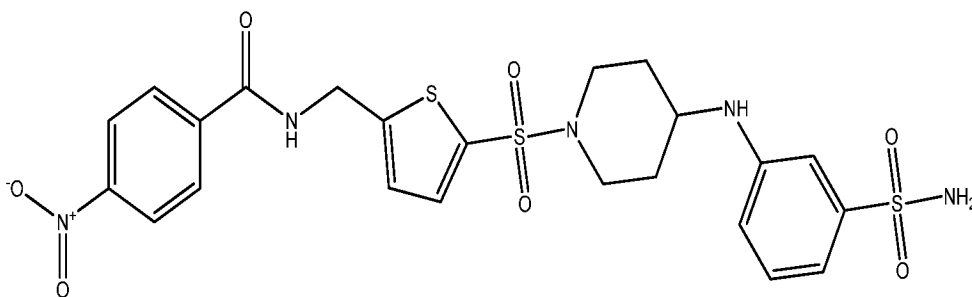
l) Claim 11 recites the limitation "4-(5,6,7,8-tetrahydronaphthalen-1-ylamino)" in the 4th species on page 20. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is heteroaryl however, the substituent R^3 is actually not heteroaryl but carbocyclic as set forth in the species below:



o) Claim 11 recites the limitation "aminosulfonyl" in the 2nd species on page 22. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is aryl substituted by SO_2NH_2 however, the aryl cannot be substituted by SO_2NH_2 as set forth in the species below:

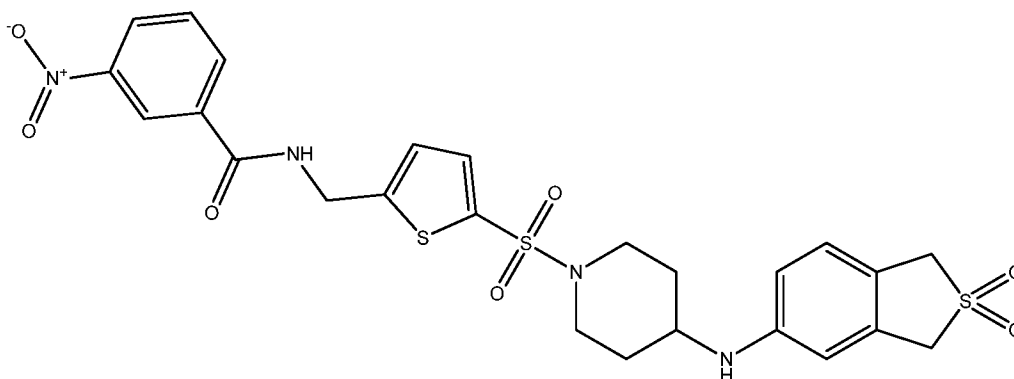


p) Claim 11 recites the limitation "aminosulfonyl" in the 1st species on page 24. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is aryl substituted by SO_2NH_2 however, the aryl cannot be substituted by SO_2NH_2 as set forth in the species below:



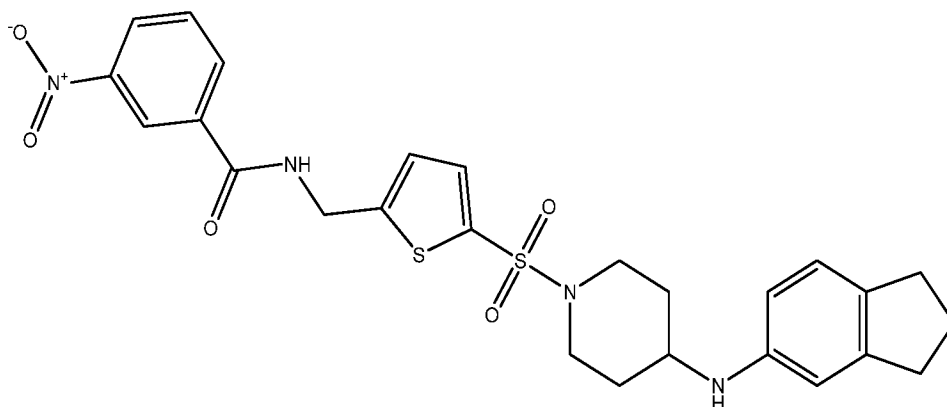
N-([5-([4-[3-(aminosulfonyl)anilino]piperidin-1-yl)sulfonyl]thien-2-yl)methyl]-4-nitrobenzamide

t) Claim 11 recites the limitation "2,2-dioxido-1,3,1,3-dihydro-2-benzothien-5-yl" in the 5th species on page 25. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is heteroaryl however, the substituent R^3 is actually not heteroaryl but heterocyclic as set forth in the species below:



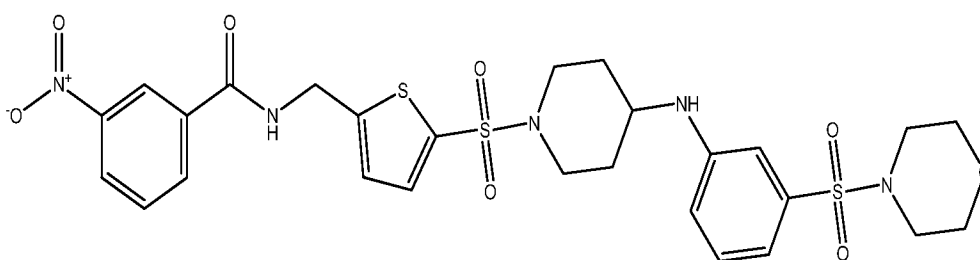
N-([5-([4-[(2,2-dioxido-1,3-dihydro-2-benzothien-5-yl)amino]piperidin-1-yl)sulfonyl]thien-2-yl)methyl]-3-nitrobenzamide

u) Claim 11 recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 1st species on page 26. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is heteroaryl however, the substituent R^3 is actually not aryl but carbocyclic as set forth in the species below:



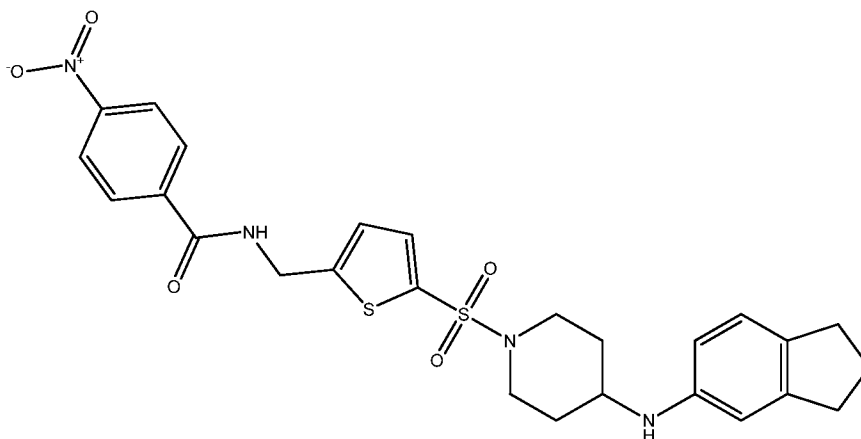
N-[(5-{[4-(2,3-dihydro-1H-inden-5-ylamino)piperidin-1-yl]sulfonyl}thien-2-yl)methyl]-3-nitrobenzamide

v) Claim 11 recites the limitation "morpholin-4-yl" in the 6th species on page 26. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is aryl substituted with sulfonyl however, the substituent R^3 is actually not aryl substituted by sulfonyl as set forth in the specification as set forth in the species below:



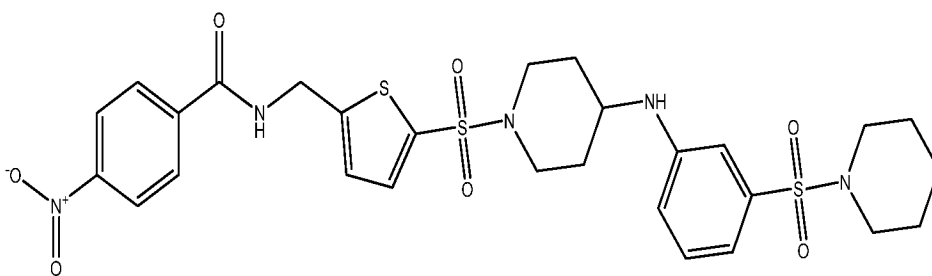
3-nitro-N-[(5-{[4-(3-(morpholin-4-ylsulfonyl)anilino)piperidin-1-yl]sulfonyl}thien-2-yl)methyl]benzamide

x) Claim 11 recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 4th species on page 27. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is heteroaryl however, the substituent R^3 is actually not heteroaryl but carbocyclic as set forth in the species below:



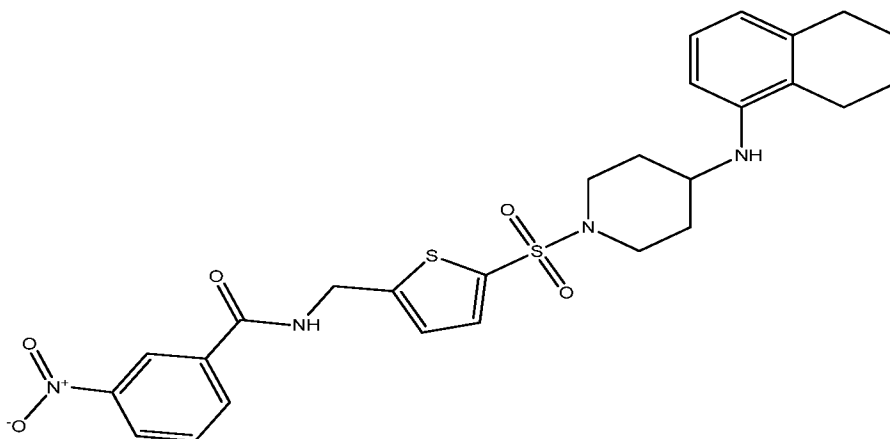
N-[(5-{[4-(2,3-dihydro-1H-inden-5-ylamino)piperidin-1-yl]sulfonyl}thien-2-yl)methyl]-4-nitrobenzamide

y) Claim 11 recites the limitation "morpholin-4-yl" in the 1st species on page 28. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is $NR^{3'}R^3$ and R^3 is aryl substituted with sulfonyl however, the substituent R^3 is actually not aryl substituted by sulfonyl as set forth in the specification as set forth in the species below:



4-nitro-N-[(5-{[4-[3-(morpholin-4-ylsulfonyl)anilino]piperidin-1-yl]sulfonyl}thien-2-yl)methyl]benzamide

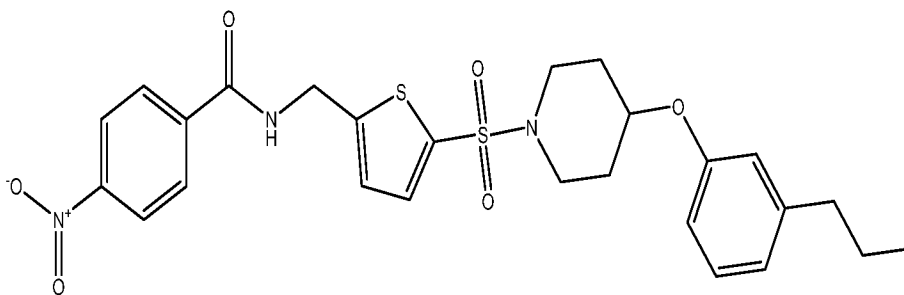
bb) Claim 11 recites the limitation "4-(5,6,7,8-tetrahydronaphthalen-1-ylamino)" in the 2nd species on page 29. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is $NR^{3'}R^3$ and R^3 is aryl however, the substituent R^3 is actually not aryl but carbocyclic as set forth in the species below:



3-nitro-N-([5-([4-(5,6,7,8-tetrahydronaphthalen-1-ylamino)piperidin-1-yl]sulfonyl)thien-2-yl)methyl]benzamide

cc) Claim 11 recites the limitation "3-propylphenoxy" in the 3rd species on page 29. There is insufficient antecedent basis for this limitation in the claim.

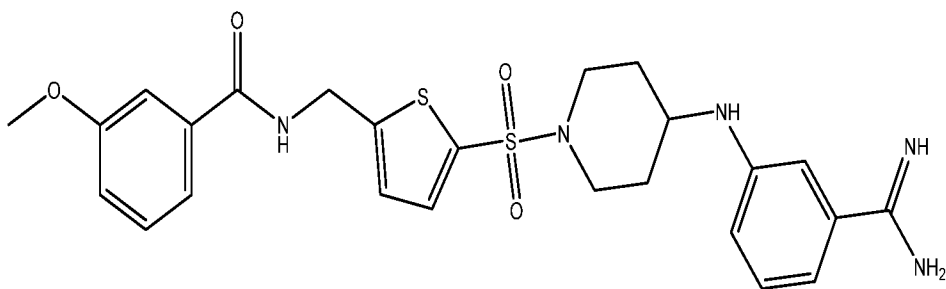
The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is aryl substituted with sulfonyl however, the substituent L^2 is actually not NR^3R^3 as set forth in the species below:



4-nitro-N-([5-([4-(3-propylphenoxy)piperidin-1-yl]sulfonyl)thien-2-yl)methyl]benzamide

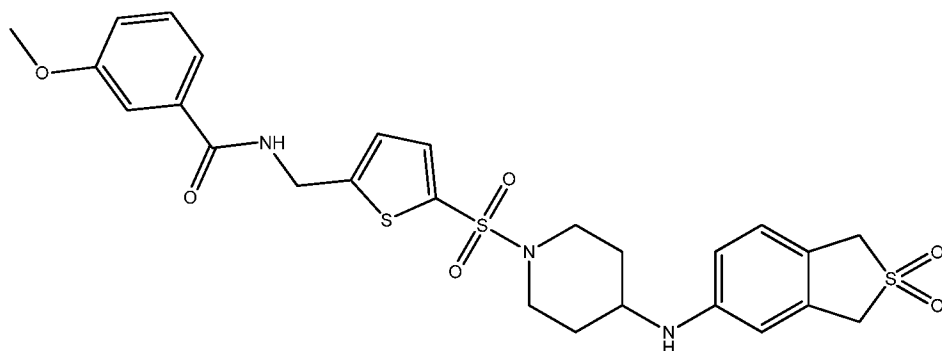
gg) Claim 11 recites the limitation "amino(imino)methyl" in the 6th species on page 31. There is insufficient antecedent basis for this limitation in the claim.

The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is aryl substituted with amino(imino)methyl however, the substituent R^3 cannot be substituted with amino(imino)methyl as set forth in the species below:



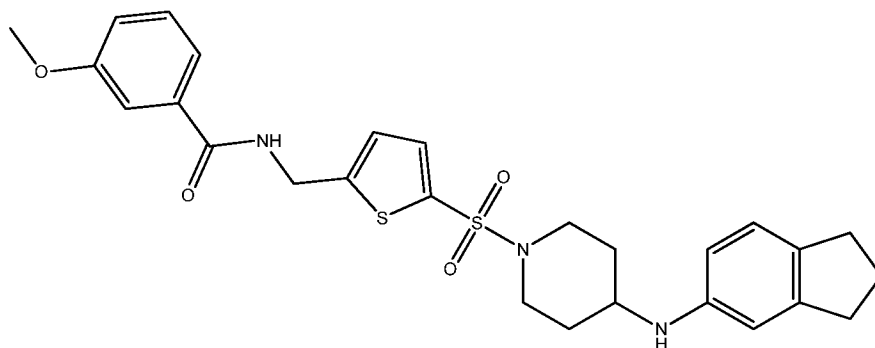
N-({5-[(4-{3-[amino(imino)methyl]anilino}piperidin-1-yl)sulfonyl]thien-2-yl}methyl)-3-methoxybenzamide

hh) Claim 11 recites the limitation "2,2-dioxido-1,3-1,3-dihydro-2-benzothien-5-yl" in the 6th species on page 32. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is heteroaryl however, the substituent R^3 is actually not heteroaryl but heterocyclic as set forth in the species below:



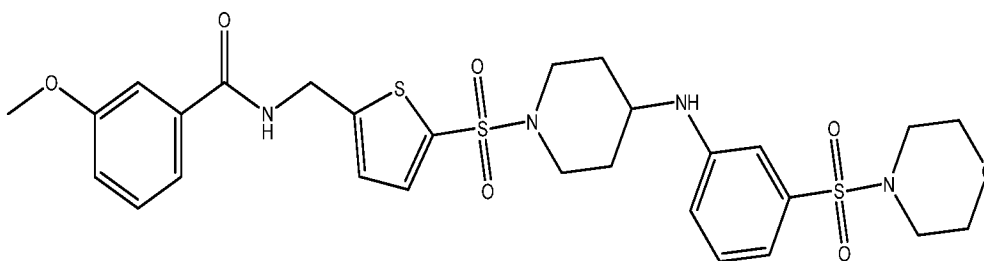
N-{[5-({4-[(2,2-dioxido-1,3-dihydro-2-benzothien-5-yl)amino]piperidin-1-yl)sulfonyl]thien-2-yl}methyl]-3-methoxybenzamide

ii) Claim 11 recites the limitation "2,3-dihydro-1H-inden-5-yl" in the 7th species on page 32. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is heteroaryl however, the substituent R^3 is actually not aryl but carbocyclic as set forth in the species below:



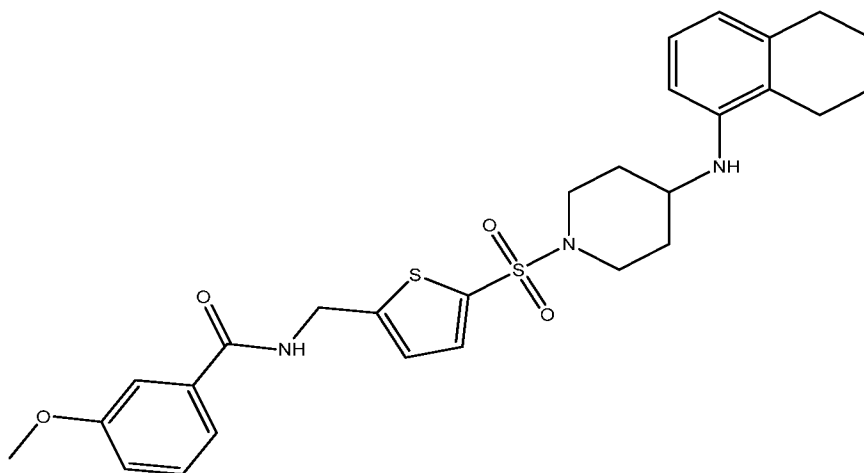
N-[(5-{[4-(2,3-dihydro-1H-inden-5-ylamino)piperidin-1-yl]sulfonyl}thien-2-yl)methyl]-3-methoxybenzamide

kk) Claim 11 recites the limitation "morpholin-4-yl" in the 4th species on page 33. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is aryl substituted with sulfonyl however, the substituent R^3 is actually not aryl substituted by sulfonyl as set forth in the specification as set forth in the species below:



3-methoxy-N-({[5-({[4-(3-(morpholin-4-ylsulfonyl)anilino]piperidin-1-yl)sulfonyl}thien-2-yl)methyl]benzamide

nn) Claim 11 recites the limitation "4-(5,6,7,8-tetrahydronaphthalen-1-ylamino)" in the 2nd species on page 34. There is insufficient antecedent basis for this limitation in the claim. The applicants' indicated that the variables of the species are L^2 is NR^3R^3 and R^3 is aryl however, the substituent R^3 is actually not aryl but carbocyclic as set forth in the species below:



3-methoxy-N-[(5-{[4-(5,6,7,8-tetrahydronaphthalen-1-ylamino)piperidin-1-yl]sulfonyl}thien-2-yl)methyl]benzamide

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection, labeled paragraph 9) of the last office action, which is hereby **withdrawn**.

5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection, labeled paragraph 10) of the last office action, which is hereby **withdrawn**.

6. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections, labeled paragraph 11) of the last office action, which are hereby **withdrawn**.

In view of the amendment dated July 22, 2009, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2, 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the claim 2 at the top of page 6 where the compounds of formula I include the diastereoisomers is not described in the specification with respect to the genus of formula I.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 2, 5-12, 20-22, 27-31 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claim 1 recites the limitation " β position" in the second proviso. There is insufficient antecedent basis for this limitation in the claim.

b. Claim 1 recites the limitation " α position" in the final proviso. There is insufficient antecedent basis for this limitation in the claim.

c. Claim 1 recites the limitation "C₁-C₆-alkyl aryl or C₁-C₆-alkyl heteroaryl" in the final proviso. There is insufficient antecedent basis for this limitation in the claim.

- d. Claim 2 recites the limitation " β position" in the second proviso. There is insufficient antecedent basis for this limitation in the claim.
- e. Claim 2 recites the limitation " α position" in the final proviso. There is insufficient antecedent basis for this limitation in the claim.
- f. Claim 2 recites the limitation "C₁-C₆-alkyl aryl or C₁-C₆-alkyl heteroaryl" in the final proviso. There is insufficient antecedent basis for this limitation in the claim.
- g. Claim 9 is vague and indefinite in that it is not known what is meant by (R⁶)_n, is selected from the group consisting of hydrogen,
- h. Claim 9 recites the limitation "-NR³C(O)R³" in the definition of L¹ and L². There is insufficient antecedent basis for this limitation in the claim.
- i. Claim 9 recites the limitation "-NR³C(O)NR³R³" in the definition of L¹ and L². There is insufficient antecedent basis for this limitation in the claim.
- j. Claim 11 recites the limitation "hydroxy" in the definition of L¹ and L². There is insufficient antecedent basis for this limitation in the claim.
- k. Claim 11 recites the limitation "4-(5-thien-2-yl-1H-pyrazol-3-yl)" in the definition of L¹ and L². There is insufficient antecedent basis for this limitation in the claim.
- l. Claim 11 is vague and indefinite in that it is not known what is meant by the and at the end of the claim.
- m. Claim 11 is vague and indefinite in that it does not end with a period.
- n. Claim 21 is vague and indefinite in that it is not known what is meant by the variable R⁶ which is not defined within the claim.

- o. Claim 21 is vague and indefinite in that it is not known what is meant by the definition of the variable R_6 where there is no variable R_6 in formula VIII.
- p. Claim 21 recites the limitation " $-NR^3C(O)NR^3R^3$ " in the definition of L^1 and L^2 . There is insufficient antecedent basis for this limitation in the claim.
- q. Claim 31 is vague and indefinite in that it is dependent upon a canceled claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624